MAR 9 2006

K052207

Incline Medical, LLC	13560 SW Willow Top Lane Tigard, OR 97224 408-850-0198

SUMMARY

Submitter's name:	Incline Medical, LLC
Address:	13560 SW Willow Top Lane Tigard, OR 97224
Phone:	408-850-0198
Name of contact person:	Greg Holland Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 Fax: 949-552-2821
Date the summary was prepared:	August 8, 2005
Trade Name:	Accurex Glucose Test Strip
Common/Usual Name:	Glucose Test System
Classification Name:	Glucose Oxidase, Glucose

The legally marketed devices to which we are claiming equivalence [807.92(a)(3)]:

One Touch Glucose Test Strip, K923544 manufactured by Lifescan Inc.

Description of the device:

The Accurex Glucose Test Strip is a generic replacement for the Lifescan One Touch Glucose Test Strip. These glucose test strips can be used with the following glucometers:

One Touch Profile
One Touch II
One Touch Basic (with large screen)
One Touch Basic (with small screen)

Indications:

The Accurex Glucose Test Strip for use with the following glucometers: One Touch, One Touch II and One Touch Basic, all manufactured by Lifescan, Inc.

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell tumors.

Summary of the technological characteristics of our device compared to the predicate device:

The Accurex Glucose Test Strip were compared to the predicate in the following areas and found to have similar technological characteristics and to be equivalent.

Indications for use
Target population
Where used
Method Comparison
Technical Comparison

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Incline Medical, LLC.
c/o Mr. Greg Holland
Regulatory Specialist
Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine, CA 92606

Re: k052207
Trade/Device Name: Accurex Glucose Test Strips
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CGA, NBW
Dated: February 27, 2006
Received: February 28, 2006

Dear Mr. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052207

Device Name: Accurex Glucose Test Strips

Indications For Use:

The Accurex Glucose Test Strip for use with the following glucometers: OneTouch Basic, OneTouch II and OneTouch Profile meters, all manufactured by Lifescan, Inc.

It is to be used for the quantitative measurement of glucose in fresh capillary whole blood. Glucose measurements are used as an aid to monitor the effectiveness of diabetes control.

Prescription Use ___ *OR* *Over-The-Counter Use* X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

(510(k)) K052207